IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of	**Kevin H. Newton, et al.**	
Serial No.:	**09/428,036**	Art Unit 3626
Confirmation No.:	**4122**	
Filed:	**October 27, 1999**	Patent Examiner Robert W. Morgan
Title:	**Method of Tracking and Dispensing Medical Items to Patients through Self Service Delivery System**	

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Commissioner for Patents
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BRIEF OF APPELLANTS
PURSUANT TO 37 C.F.R. § 1.192

Sir:

The Appellants hereby submit their Appeal Brief pursuant to 37 C.F.R. § 1.192, in triplicate, concerning the above-referenced Application.

REAL PARTY IN INTEREST

The Assignee of all right, title and interest to the above-referenced Application is MedSelect Inc., a Delaware corporation.

RELATED APPEALS AND INTERFERENCES

Appellants believe that there are no related appeals or interferences pertaining to this matter.

STATUS OF CLAIMS

Claims 1-45 are pending in the Application.

Claims 1, 10-14, and 26-27 were rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by Kraft, et al. (U.S. 5,502,944) ("Kraft").

Claims 2, 9, and 15-23 were rejected pursuant 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Liff, et al. (U.S. 5,797,515) ("Liff").

Claims 3-8 and 24-25 were rejected pursuant 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Liff and the Official Notice.

Claims 28-31, 34-37, 39, and 42-45 were rejected pursuant 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Kaufman, et al. (U.S. 5,036,416) ("Kaufman").

Claims 32-33, 40-41, and 45 were rejected pursuant 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Kaufman and Cummings, Jr. (U.S. 5,301,105) ("Cummings").

These rejections were the only rejections present in the Office Action ("Action") dated June 4, 2003, which was made Final. Appellants appeal each claim rejection, inclusive.

Additional Comments

Comment 1

The Action (on page 14) refers to Kaufman, et al. (U.S. 5,036,416). However, Kaufman, et al. (U.S. 5,036,416) is not of record. Nor does U.S. 5,036,416 correspond to an inventor named Kaufman. Therefore, the rejection based on Kaufman, et al. (U.S. 5,036,416) is unclear. It follows that the Action is unclear.

Nevertheless, Appellants desire to advance prosecution and proceed with their appeal. There is a Kaufman, et al. (U.S. 5,036,462) of record. Furthermore, as shown in more detail herein, the application of Kaufman, et al. (U.S. 5,036,462) does not render claims 28-31, 34-37, 39, and 42-45 obvious. Thus, to prevent unnecessary prosecution delay by the Office, claims 28-31, 34-37, 39, and 42-45 have been presumed to be rejected pursuant 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Kaufman, et al. (U.S. 5,036,462) ("Kaufman"). That is, reference to Kaufman (U.S. 5,036,416) in the Action is presumed by Appellants to be a typographical error, with the correct reference being to Kaufman (U.S. 5,036,462). The Appellants reserve all rights to amend their arguments, including the filing of a Supplemental Appeal Brief, if their presumption, required by the unclear Action, is incorrect.

Comment 2

Claim 38 does not stand formally rejected. No rejection heading includes claim 38. However, the Office Action cover sheet indicates that claims 1-45 are rejected. The Action (on

page 21) also refers to claim 38 in the body of the Kraft/Kaufman rejection. Thus, the status of claim 38 (allowed or rejected) is unclear. It follows that the Action is unclear.

Again, in order to advance prosecution and prevent unnecessary prosecution delay by the Office, claim 38 has been presumed to be rejected pursuant 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Kaufman. The Appellants reserve all rights to amend their arguments, including the filing of a Supplemental Appeal Brief, if their presumption, required by the unclear Action, is incorrect.

Comment 3

The Action (on page 14) refers to claims 28-31, 34-37, 39, and 42-45 being unpatentable over Kraft in view of Kaufman. The Action (on page 22) also refers to claims 32-33, 40-41, and 45 as being unpatentable over Kraft in view of Kaufman and Cummings. That is, the rejection headings indicate claim 45 as being rejected twice. However, the rejection based on Kraft/Kaufman does not address claim 45 in the body of the rejection. Furthermore, the reliance on an additional reference (Cummings) in the Kraft/Kaufman/Cummings rejection infers that claim 45 is not obvious in view of only Kraft/Kaufman. Thus, the pending rejection against claim 45 is unclear. It follows that the Action is unclear.

Nevertheless, as shown in more detail herein, claim 45 is not obvious in view of Kraft/Kaufman/Cummings. It follows that claim 45 cannot be obvious in view of only Kraft/Kaufman. Again, in order to advance prosecution and prevent unnecessary prosecution delay by the Office, claim 45 has been presumed not to be rejected as obvious over Kraft/Kaufman, but rather only rejected as obvious in view of Kraft/Kaufman/Cummings. The

Appellants reserve all rights to amend their arguments, including the filing of a Supplemental Appeal Brief, if their presumption, required by the unclear Action, is incorrect.

STATUS OF AMENDMENTS

A final rejection was made June 4, 2003. No amendments to the claims were requested to be admitted after the final rejection.

SUMMARY OF INVENTION

Overview of the Invention

An exemplary form of the invention is directed to a method of dispensing a patient-requested medical item from a patient-accessible self-service medical item dispenser, verifying that medical item was dispensed to the patient, and recording the verified dispense. An exemplary embodiment (e.g., 700; Figure 63) includes recording data in a data store representative of each of (1) a plurality of medical item storage locations in the patient-accessible self-service medical item dispenser (718), (2) a plurality of types of medical items, (3) the type of medical item stored in each respective storage location, (4) plural patients, and (5) at least one medical item type prescribed for use by at least one patient. The exemplary embodiment further includes receiving from a patient through an input device (e.g., keypad 724) of the dispenser (718) both patient identification data and a patient request to dispense a medical item type prescribed for use by the patient. The dispenser (718) includes a card reader device (726) enabling the reading a patient's credit card (734) or debit card (736). The dispenser card reader device enables a patient to pay (e.g., the co-payment) for the requested medical item type. The

dispenser is able to dispense the requested medical item type to the patient. The dispenser is further able to verify that the requested medical item type was actually dispensed to the patient. Verification can be via a sensor (179) transmitting a signal to a computer responsive to sensing the requested medical item type passing the sensor as it was dispensed. Responsive to a verified dispense, data can be stored linking each of the patient, the verified dispensed medical item type, and the storage location in the dispenser of the verified dispensed medical item type. Verification of a dispensed medical item permits minimizing the risk of falsely recording a dispense which did not actually occur, such as due to a malfunction (e.g., Specification page 127, lines 5-12; page 123, lines 8-10; and page 154, lines 14-22).

The operation of the system (700) of the exemplary embodiment is represented in the logic flow shown in Figures 64-67. In the exemplary method of operation, a benefit plan associated with the patient is determined from rules stored in connection with data representative of the benefit plan. Payment for dispensed medications is provided by the benefits provider associated with the patient's benefit plan and a co-payment is made by the patient from a credit or debit card account via the dispenser prior to the requested dispensing.

CONCISE STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

The questions presented in this appeal are:

1). Whether Appellants' claims 1, 10-14, and 26-27 are unpatentable under 35 U.S.C. § 102(e) as being anticipated by Kraft.

2). Whether Appellants' claims 2, 9, and 15-23 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Liff.

3). Whether Appellants' claims 3-8 and 24-25 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Liff and the Official Notice.

4). Whether Appellants' claims 28-31, 34-37, 39, and 42-45 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Kaufman.

5). Whether Appellants' claims 32-33, 40-41, and 45 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Kaufman and Cummings.

GROUPING OF CLAIMS

No groups of claims stand or fall together. Every claim recites additional features of the invention which distinguishes the claim over every other pending claim.

Each of Appellants' claims recites at least one element or combination of elements not found or suggested in the applied references, which patentably distinguishes the claims.

The pending claims include three independent claims (claims 1, 34, and 45). Claims 2-33 depend from claim 1. Claims 35-44 depend from claim 34. All pending claims 1-45 are reproduced in the Appendix.

ARGUMENT

The Applicable Legal Standards

Anticipation pursuant to 35 U.S.C. § 102 requires that a single prior art reference contain all the elements of the claimed invention arranged in the manner recited in the claim. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983).

Anticipation under 35 U.S.C. § 102 requires in a single prior art disclosure, each and every element of the claimed invention arranged in a manner such that the reference would literally infringe the claims at issue if made later in time. *Lewmar Marine, Inc. v. Barient, Inc.*, 822 F.2d 744, 747, 3 USPQ2d 1766, 1768 (Fed. Cir. 1987).

Anticipation by inherency requires that the Patent Office establish that persons skilled in the art would recognize that the missing element is necessarily present in the reference. To establish inherency the Office must prove through citation to prior art that the feature alleged to be inherent is "necessarily present" in a cited reference. Inherency may not be established based on probabilities or possibilities. It is plainly improper to reject a claim on the basis of 35 U.S.C. § 102 based merely on the possibility that a particular prior art disclosure could or might be used or operated in the manner recited in the claim. *In re Robertson*, 169 F.3d 743, 49 U.S.P.Q. 2d 1949 (Fed. Cir. 1999).

Before a claim may be rejected on the basis of obviousness pursuant to 35 U.S.C. § 103, the Patent Office bears the burden of establishing that all the recited features of the claim are known in the prior art. This is known as *prima facie* obviousness. To establish *prima facie* obviousness, it must be shown that all the elements and relationships recited in the claim are known in the prior art. If the Office does not produce a *prima facie* case, then the Appellants are under no obligation to submit evidence of nonobviousness. MPEP § 2142.

The teaching, suggestion, or motivation to combine the features in prior art references must be clearly and particularly identified in such prior art to support a rejection on the basis of obviousness. It is not sufficient to offer a broad range of sources and make conclusory statements. *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

Even if all of the features recited in the claim are known in the prior art, it is still not proper to reject a claim on the basis of obviousness unless there is a specific teaching, suggestion, or motivation in the prior art to produce the claimed combination. *Panduit Corp. v. Denison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593 (Fed. Cir. 1987). *In re Newell*, 891 F.2d 899, 901, 902, 13 USPQ2d 1248, 1250 (Fed. Cir. 1989).

The evidence of record must teach or suggest the recited features. An assertion of basic knowledge and common sense not based on any evidence in the record lacks substantial evidence support. *In re Zurko*, 258 F.3d 1379, 59 USPQ2d 1693 (Fed. Cir. 2001).

A determination of patentability must be based on evidence of record. *In re Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002).

It is respectfully submitted that the Action from which this appeal is taken does not meet these burdens.

The Kraft Reference

Kraft is directed to a medication dispensing in a hospital. Kraft provides secure medical dispensing "to nurses in a hospital setting" (col. 1, lines 5-8). Kraft requires a secure environment (e.g., col. 13, lines 64-66; col. 1, lines 56-67). Kraft's dispenser (12) is located at a hospital nursing station (col. 3, lines 63-66; col. 5, lines 61-62). Only authorized personnel are permitted to use the dispenser. A nurse must enter authorized identification, such as a secret password, in order to obtain medication from the dispenser (12) (col. 5, lines 8-11).

The dispenser (12) comprises a plurality of containers (90, 130) for holding medication units. As shown in Figure 3, the dispenser (12) also comprises a packaging subsystem (38) for

containing one or more medication units in a package (306), and robotics subsystem (40) for manipulating a selected container to transfer one or more medication units from the container directly to a package. Kraft's arrangement permits direct transfer of medication from a container to a package so no cross-contamination occurs (col. 2, lines 14-17; col. 14, lines 6-7).

The Liff Reference

Liff is directed to an automated drug dispensing system. The system is for use outside of a hospital (col. 2, lines 2-5). The system includes a cabinet (20) adapted to store a variety of prepackaged pharmaceuticals in a plurality of bins (34) for filling patient prescriptions. Each bin stores a particular variety of packages (32) containing pharmaceuticals. Each variety of pharmaceutical is associated with a particular bar code (98) marked on the package (32). When the prepackaged items are loaded into the system, a loader scans each bar coded package with a bar code reader (40) so that the database properly reflects the loaded packages.

Each bin (34) includes a dispenser (68). The dispenser (68) can release a single package of the variety requested. A licensed user (e.g., a doctor, pharmacist, nurse, or other medical practitioner qualified to fill patient prescriptions) operates the system (col. 5, lines 19-23). After a package (32, 74) is dispensed, the bar code reader (40) determines the code (98) on the dispensed package, and verifies whether the code on the dispensed package matches the code of the requested package.

The Kaufman Reference

Kaufman is directed to a system for medical dispensing in a "home, outside the support system of a hospital", and without the "supervision of medical personnel" (col. 1, lines 10-14). Kaufman's system includes a plurality of in-home specific features that are directed to long-term care. For example, Kaufman permits medication to be dispensed (20) upon demand by the patient (e.g., col. 9, lines 17-25). A patient can apply medication dispense commands via a speech recognition system (56) (col. 9, lines 48-53).

In a further example of Kaufman's in-home specific features (e.g., Kaufman's abstract), the system can measure a preselected physical parameter of a patient as well as a preselected parameter in the patient's immediate environment (home's heating and cooling system; col. 7, lines 5-15). A control element can compare the measured preselected physical parameter with the measured preselected environmental parameter. A first command signal can be generated when a predetermined correlation exists between the two parameters, while a second command signal can be generated when it does not. The command signal can be used to base a decision to dispense (20) medication (44) to the patient, or to change the patient's immediate environment (e.g., col. 6, lines 54-66; col. 7, lines 10-13).

The Cummings Reference

Cummings is directed to a fully integrated and comprehensive health care management system. The system includes an integrated interconnection and interaction of the patient, health care provider, bank, insurance company, utilization reviewer, and employer so as to include within a single system each of the essential participants to provide patients with complete and

comprehensive pre-treatment, treatment, and post-treatment health care and predetermined financial support therefor.

The system includes physician office terminals (11a-11c) (col. 4, lines 7-10) for utilization of the system by a physician. The terminals (11a-11c) are conventional data input terminals, such as shown in Figure 2 (col. 4, lines 10-14). The terminals (11a-11c) are located within the physician's office (col. 7, line 55). The terminals (11a-11c) have a card data entry slot (52) (col. 7, lines 17-19) enabling use a credit card in place of a personnel identification card for purpose of identification (col. 4, lines 40-46), and enabling use a credit card for the purpose of data entry (col. 7, lines 25-38).

(iii) 35 U.S.C. § 102

In the Action claims 1, 10-14, and 26-27 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kraft. These rejections are respectfully traversed.

Appellants respectfully disagree with the Action's interpretation of Kraft. As shown in more detail herein, Kraft does not teach each and every feature, relationship, and step of the claimed invention arranged in the manner recited in the claims, as is required to sustain the rejections. It follows that Kraft cannot anticipate the claims. Thus, it is respectfully submitted that the 35 U.S.C. § 102(e) rejections should be withdrawn.

Claim 1

Kraft does not teach at least the combination of steps (d) and (e). It follows that Kraft cannot anticipate claim 1.

Step (d) of claim 1 recites "dispensing" from the dispenser the type medical item prescribed for use by the patient. Step (e) of claim 1 further recites, responsive to execution of step (d), including in the data store data representative that the type medical item has been dispensed for use by the patient, and that the type medical item has been dispensed from the dispenser.

Kraft does not teach including in a data store "data representative that the type medical item has been dispensed for use by the patient, and that the type medical item has been dispensed from the dispenser" (claim 1, step e).

Kraft does not store (record) data that a medical item "has been dispensed" responsive to a "dispensing" (step d). Kraft indicates that as an individual medication is being dispensed, the system controller (34) records "information" (col. 5, lines 6-7). Apparently, this "information" relates to the patient (col. 5, lines 1-6). However, there is no evidence of recording that the medical item "has been dispensed" (step e). Kraft does not include in a data store data that a medical item "has been dispensed," responsive to "execution" of the "dispensing" (step d) of the medical item from the dispenser. Where does Kraft record that a medical item has been dispensed in response to (after) an executed dispense? Kraft teaches no link between verifying that a medical item was actually dispensed and the recording of the medical item type.

Kraft does not check (or know) if an item was in fact dispensed. Thus, Kraft would record an item that was not actually dispensed (e.g., due to a dispensing malfunction). In contrast, the invention of claim 1 minimizes the risk of falsely recording a dispense which did not actually occur due to a malfunction (e.g., Specification page 127, lines 5-12; page 123, lines 8-10; and page 154, lines 14-22).

In Kraft the dispensing process is initiated by a nurse who enters a command though the system controller (34) to retrieve medication for a patient (col. 4, lines 53-66). Once the nurse orders the medication, the dispenser (12) attempts to retrieve and dispense the medication. In response to the dispense request, the system controller (34) records a dispense for a patient (col. 5, lines 6-7). That is, an unverified dispense is recorded. Note Kraft's references to the recording occurring as "medication is dispensed" (col. 5, lines 6-7) and as "medications are dispensed" (col. 5, lines 49-52). Even Kraft's database is updated as medication is (supposedly) being dispensed (col. 6, lines 32-34). Even the Action (pages 28-29, paragraph B) acknowledges that Kraft records a dispense "as medications are dispensed" (page 29, lines 2-3) and as a medication is "being dispensed" (page 29, lines 9-10). How can data that a medical item "has been dispensed" be recorded in Kraft when recordation in Kraft occurs before the dispensing is complete? Kraft records a dispense responsive to a dispense request, not responsive to execution of an actual dispensing (step d).

The "including" of recited step (e) is "responsive to execution of step (d)." Step (d) recites the actual "dispensing from the dispenser." Kraft does not record a dispense after the dispense has occurred. Kraft at best records an unverified dispense while the dispense is (supposedly) still occurring, whereas step (e) records a dispense that has occurred. Note Kraft's present tense use of "is" versus the recited past tense use of "has been". It follows that Kraft does not teach "that the type medical item has been dispensed." It further follows that Kraft does not teach "that the type medical item has been dispensed for use by the patient." Thus, Kraft does not anticipate claim 1.

Nor does Kraft record information that a "medical item has been dispensed from the dispenser." For example, claim 1 recites "a medical item dispenser" (step b) and refers back to "the dispenser" in steps (c), (d), and (e). Claim 1, at step (e), recites "including in the data store . . . that the type medical item has been dispensed from the dispenser." For example, note the Specification at page 8, lines 2-4; page 29, lines 2-9; page 30, lines 14-22; page 52, line 22 to page 53, line 1; and page 154, lines 14-22. Where does Kraft record information that a particular type of medical item has been actually dispensed from a specific dispenser? Kraft does not teach the recited features, relationships, and steps. Nor does Kraft anticipate claim 1.

Kraft does have pill detection means, e.g., via optic systems (124, 126) and a light detector (340), but these detection means are not associated with recording that a pill was actually dispensed. The optic systems include a container identification optics (126) and singulation optics (124) (col. 7, lines 26-43). The container identification optics (126) merely reads a container label to identify the container contents. The singulation optics (124) detects (160) for preloaded pills in a holding area (152) of a container (130) prior to any dispensing request (col. 8, lines 13-15 and 39-67). The detection is not recorded. Nor is the detection associated with recording that a pill was actually dispensed.

Kraft uses singulation optics to verify that a single pill is preloaded in the holding area (152) prior to an initiated dispense (col. 8, lines 8-17; col. 10, lines 17-24). A discharge ramp (154) is associated with the holding area (152) (col. 8, lines 2-3; Figure 9). In Kraft a container (90, 130) is rotated to drop (discharge) a medication therefrom (col. 12, lines 58-59). Kraft is concerned with verifying the preloading of a pill in a correct location to ensure that the pill is

staged to be dispensed from the container (col. 7, lines 39-41). Kraft is concerned with preloading verification. Kraft is not concerned with recordation of post-dispensing verification.

Kraft's light detector (340) can determine whether a pill from a container (130) has landed in a package (col. 12, line 58 to col. 13, line 3). However, the detection is only used to cause operation of a package drive (342) and sealing of the package. The detection is not recorded. Nor is the detection associated with recording that a pill was actually dispensed. Contrarily, for the reasons previously discussed, Kraft could record a pill dispense prior to (or without) operation of the light detector (340).

Kraft does not teach both recording that a type medical item has been dispensed for use by the patient and recording that the type medical item has been dispensed from the dispenser. The Appellants respectfully submit that Kraft does not teach every feature, relationship, and step arranged in the manner recited in claim 1, as is required to sustain the rejection. Thus, Appellant respectfully submits the 35 U.S.C. § 102(e) rejection of claim 1 is improper and should be withdrawn.

Claim 10

Claim 10 depends from claim 1. The Action refers to Kraft's video display (26) as the recited output device. However, where does Kraft specifically teach displaying, on the video display (26), indicia indicative of a medical item type? What requires the video display (26) to display indicia indicative of a medical item type? What prevents the video display (26) from displaying only a patient's information (e.g., name, ID number)? Kraft does not anticipate claim 10.

Claim 11

Claim 11 depends from claim 10. Kraft does not teach inputting an agreement with display indicia. The relied upon section (col. 4, lines 54-56) of Kraft is not relevant to receiving an input through an input device indicating agreement with display indicia. Kraft does not anticipate claim 11.

Claim 12

Claim 12 depends from claim 11/10/1. Kraft further does not teach displaying indicia indicative of a medical condition for which the medical item has been prescribed. The Action refers to information on a label, not displaying medical condition information on an output device. Where does Kraft teach displaying medical condition information on the video display (26)?

Furthermore, where does Kraft teach inputting prescription data through a physician terminal in operative connection with the computer? Kraft teaches that medication orders are initiated by a physician, but in response to the physician's request a pharmacist enters information into a hospital's computer system (col. 1, lines 14-18). It follows that Kraft does not anticipate claim 12.

Claim 13

Claim 13 depends from claim 11/10/1. The Action (regarding claim 10) refers to Kraft's video display (26) as the recited output device. Where does Kraft teach displaying indicia indicative of a physician name on the video display (26)? Where does Kraft teach inputting prescription data through a physician terminal in operative connection with the computer? It follows that Kraft does not anticipate claim 13.

Claim 14

Claim 14 depends from claim 13/11/10/1. Kraft further does not teach applying indicia (indicative of the physician name) in connection with a dispensed type medical item in the manner recited. Nor does Kraft anticipate claim 14.

Claim 26

Claim 26 depends from claim 1. Kraft further does not teach checking data representative of a medical history of the patient. Where does Kraft even mention the medical history of a patient? The Action refers to Kraft's optic systems. However, Kraft's use of optics to check for preloading of medication prior to dispensing is unrelated to checking the medical history of a patient. Nor does Kraft teach determining responsive to the medical history if a medical item should be withheld from the patient. It follows that Kraft does not anticipate claim 26.

Claim 27

Claim 27 depends from claim 26. Kraft further does not teach checking medical history by communicating over a public data network. Nor does Kraft anticipate claim 27.

(iv) 35 U.S.C. § 103

Appellants traverse the rejections. The Appellants respectfully submit that the attempts to combine the teachings of the references are clearly attempts at hindsight reconstruction of Appellants' claimed invention, which is legally impermissible and does not constitute a valid basis for a finding of obviousness. *In re Fritch*, 22 USPQ2d 1780 (Fed. Cir. 1992). The rejections, which lack the necessary evidence and rationale, are based on knowledge gleaned only from Appellants' disclosure. There is no teaching, suggestion, or motivation cited so as to

produce Appellants' invention. Furthermore, without a motivation to combine, which is the current situation, a rejection based on a *prima facie* case of obviousness is improper (MPEP § 2143.01). The Office does not factually support any *prima facie* conclusion of obviousness. It would not have been obvious to one having ordinary skill in the art to have modified the references in the manner alleged to have produced the recited invention. Thus, it is respectfully submitted that the 35 U.S.C. § 103(a) rejections are improper and should be withdrawn.

The Pending Claims Are Not Obvious Over
Kraft in view of Liff

Claims 2, 9, and 15-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Liff. These rejections are respectfully traversed. The Appellants respectfully disagree with the Office's interpretation and application of the references.

Liff Does Not Constitute Prior Art

For purposes of 35 U.S.C. § 103(a) the Liff reference has a filing date of May 3, 1996 and claims priority as a continuation-in-part of U.S. Patent No. 5,713,485 filed October 18, 1995. However, the present invention is entitled to an earlier priority. The present invention claims priority to at least the December 16, 1994 filing date of U.S. Application No. 08/361,783 (U.S. Patent No. 5,790,409 to Fedor). Fedor supports steps (a)-(e) recited in claim 1. For example, note step (a) support in Fedor at col. 3, lines 20-37, col. 9, lines 1-33, and col. 16, lines 46-63; step (b) support at col. 10, lines 56-67; step (c) support at col. 8, lines 59-67; step (d) support at col. 18, lines 20-22; and step (e) support at col. 20, lines 17-29. The Action did not rebut this previously presented showing of support in Fedor.

Appellants have shown that the Liff reference does not constitute prior art to the subject matter of claim 1. Claims 2-9 and 15-25 include the subject matter of claim 1. Thus, Liff does not constitute prior art to the subject matter of claims 2-9 and 15-25. Appellants "may overcome a 35 U.S.C. § 103 rejection based on a combination of references by showing completion of the invention by applicant prior to the effective date of any of the references" (MPEP § 715.02). Therefore, any rejection involving the Liff reference is invalid. Therefore, it is respectfully submitted that the 35 U.S.C. § 103(a) rejections of claims 2-9 and 15-25 should be withdrawn.

The statements in the Action itself further support that the obviousness type rejections of claims 2-9 and 15-25 based on Liff are invalid. This is because the Action contends that any differences between the claimed invention of claims 2-9 and 15-25 and that of claim 1 (which finds support in the Fedor reference) "would have been obvious to one of ordinary skill in the art" in view of the prior art (MPEP § 715.02). Appellants' possession of what is shown (in Fedor prior to the filing date of Liff) carries with it possession of variations and adaptations of the Fedor teaching which would have been obvious to one of ordinary skill in the art (MPEP § 715.02). The claims 2-9 and 15-25, which the Office contends are obvious from the subject matter recited in claim 1, are thereby allowable.

The admitted limited availability of Liff as prior art

The Action states (on page 29) that "Liff was only relied on for the data representative of a benefit plan associated with the patient, and payment rules concerning payment for medication items associated with the benefit plan and the step of charging for the dispensed medical item in accordance with the payment rules." The Action admits (on page 29), because of the limited

availability of Liff as prior art, that Liff is only used in the particular limitation regarding a benefit plan or payment rules associated with a benefit plan.

This is not consistent with the rejections asserted in the Action. Only claims 2, 4-6, and 9 refer to particular features to which the Office has limited the application of Liff. Thus, by the Office's own admission, the reliance on Liff for the features of claims 15-23 is improper. Therefore, it is respectfully submitted that the 35 U.S.C. § 103(a) rejections of claims 15-23 should be withdrawn.

Claim 2

Claim 2 depends from claim 1. The Action (on page 6) further admits that Kraft does not teach or suggest data representative of a benefit plan or payment rules associated with the benefit plan. The Appellants respectfully disagree with the Office's assessment of the Liff teaching. Where does Liff even mention a benefit plan? The Office has not established a *prima facie* case of obviousness.

Claim 9

Claim 9 depends from claim 1. As previously discussed, the Action admits that Kraft does not teach or suggest data representative of a benefit plan or payment rules associated with the benefit plan. Liff does not mention a benefit plan. Neither reference teaches or suggests determining a benefit plan associated with a patient, and charging for a medical item in accordance with payment rules associated with the benefit plan determined to be associated with the patient. The Office has not established a *prima facie* case of obviousness.

Claim 15

Claim 15 depends from claim 14/13/11/10/1. Neither of the references, taken alone or in combination, teach or suggest storing data indicative of an instruction for using the type medical item in the manner recited.

Claim 16

Claim 16 depends from claim 1. The Action apparently relies only on Kraft. However, as previously discussed, Kraft does teach or suggest the recited subject matter. Kraft does not teach or suggest inputting prescription data through a physician terminal. Note Appellants' remarks regarding claim 12. The Office has not established a *prima facie* case of obviousness. It would not have been obvious to one having ordinary skill in the art to have modified the references in the manner alleged to have produced the recited invention.

Claim 17

Claim 17 depends from claim 16. Neither of the references, taken alone or in combination, teach or suggest applying indicia indicative of data included in the prescription data (inputted through a physician terminal) to a type medical item in the manner recited.

Claim 18

Claim 18 depends from claim 17/16/1. Neither of the references, taken alone or in combination, teach or suggest applying indicia indicative of an instruction to the medical item. Note Appellants' remarks regarding claim 15.

Claim 19

Claim 19 depends from claim 17/16/1. Neither of the references, taken alone or in combination, teach or suggest applying a prescription label that includes indicia indicative of the

data included in the prescription data (inputted through a physician terminal) in the manner recited.

Claim 20

Claim 20 depends from claim 17/16/1. Neither of the references, taken alone or in combination, teach or suggest that indicia indicative of data included in prescription data (inputted through a physician terminal) is applied to the type medical item to be dispensed.

Claim 21

Claim 21 depends from claim 19/17/16/1. Neither of the references, taken alone or in combination, teach or suggest the recited order of steps.

Claim 22

Claim 22 depends from claim 21/19/17/16/1. Neither of the references, taken alone or in combination, teach or suggest sensing the taking of a label, especially after execution of dispensing, and preventing further dispensing until the label is sensed as taken. The relied upon section of Liff is unrelated to the recited subject matter. Where does Liff teach or suggest sensing the taking of a label? Neither of the references, taken alone or in combination, teach or suggest the recited features, relationships, and steps. The Office has not established a *prima facie* case of obviousness.

Claim 23

Claim 23 depends from claim 1. As previously discussed, neither of the references, taken alone or in combination, teach or suggest steps (a) through (e) for one patient. It follows that neither of the references, taken alone or in combination, teach or suggest steps (a) through (e) for a plurality of patients represented in the data store. It would not have been obvious to one having

ordinary skill in the art to have modified the references in the manner alleged to have produced the recited invention.

The Pending Claims Are Not Obvious Over
Kraft in view of Liff and the Official Notice

Claims 3-8 and 24-25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Liff and the Official Notice. These rejections are respectfully traversed.

As previously discussed, Liff does not constitute prior art to the subject matter of claims 3-8 and 24-25. Furthermore, as previously discussed, by the Office's own admission (on page 29), the reliance on Liff for the features of claims 3, 7-8, and 24-25 is improper. Note Appellants' previous remarks regarding the improper use of Liff in the rejections based on "Kraft in view of Liff."

Additionally, the Patent Office is not permitted to rely on unsupported assertions as the basis for rejecting claims. Applicants challenge the Action's "Official Notice" assertion of prior art teachings. Additionally, an assertion (i.e., the Official Notice assertion) not based on any prior art evidence in the record, which is the current situation, lacks substantial evidence support. Rather, the Office must point to some concrete evidence in the record. *In re Zurko,* supra. A determination of patentability must be based on evidence of record. *In re Lee*, supra. Appellants respectfully submit that the record lacks the requisite supporting evidence. It follows that the rejections do not factually support any *prima facie* conclusion of obviousness.

Claim 3

Claim 3 depends from claim 2. The Action (on page 11) admits that Kraft/Liff fails to teach or suggest reading a credit or debit card with a card reading device adjacent a medical item dispenser, wherein the card reading device is in operative connection with the computer, and charging an account associated with the credit or debit card. The Action relies on an "Official Notice." However, the record lacks evidence of the alleged prior art teaching. For example, where is a prior art teaching of a (credit or debit) card reading device adjacent a medical item dispenser? Thus, the record lacks substantial evidence support. The determination of patentability is not based on evidence of record, as is required. *In re Lee*, supra. *In re Zurko*, supra. Appellants respectfully submit that in light of the admitted failure of Kraft/Liff to teach or suggest all of the recited features and relationships, combined with the lack of any other supporting evidence of record, the rejection is not valid.

The Action (on page 11) further alleges that it would have been obvious to permit use of a customer's (i.e., patient's) credit card with the system of Kraft/Liff to enable customers to make purchase and payment for medicine. The Appellants respectfully disagree. The primary reference to Kraft is directed to providing secure medical dispensing "to nurses in a hospital setting" (col. 1, lines 5-8). Kraft requires a secure environment (e.g., col. 13, lines 64-66; col. 1, lines 56-67). Kraft's dispenser (12) is located at a hospital nursing station (col. 3, lines 63-66; col. 5, lines 61-62). That is, the dispenser (12) is specifically located away from a patient's room. Even a nurse must enter authorized identification, such as a secret password, in order to obtain medication from the dispenser (12) (col. 5, lines 8-11). Thus, Kraft explicitly teaches against the dispenser (12) dispensing a medical item to a patient. Furthermore, how could an incapacitated

patient use a credit card to charge needed medication from a dispenser located in a nurses' station? One having ordinary skill in the art would not have found it obvious to have modified Kraft/Liff with the alleged teaching of the "Official Notice" to have produced the recited invention.

Claim 4

Claim 4 depends from claim 2. The Action (on page 12) admits that Kraft/Liff fails to teach or suggest charging a benefits provider. Again, the Action relies on an "Official Notice" for the admittedly absent features and relationships. Again, the record lacks substantial evidence support. *In re Zurko*, supra. Nor is the determination of patentability based on evidence of record. *In re Lee*, supra. It follows that the rejections do not factually support any *prima facie* conclusion of obviousness.

Claim 5

Claim 5 depends from claim 3/2/1. Again, the record lacks substantial evidence support. Again, the determination of patentability is not based on evidence of record. *In re Zurko*, supra. *In re Lee*, supra. It follows that the rejections do not factually support any *prima facie* conclusion of obviousness.

Claim 6

Claim 6 depends from claim 5/3/2/1. Again, the record lacks substantial evidence support. Again, the determination of patentability is not based on evidence of record. *In re Zurko*, supra. *In re Lee*, supra. It follows that the rejections do not factually support any *prima facie* conclusion of obviousness.

Claim 7

Claim 7 depends from claim 5/3/2/1. The Action (on page 12) admits that Kraft/Liff fails to teach the recited features and relationships (e.g., outputting indicia representative of the co-pay amount). The Action (on page 13) then apparently alleges that it would be obvious to combine the teachings of Kraft and Liff. However, even if the teachings of Kraft and Liff were combined as alleged, Kraft/Liff would still fail to teach the recited features and relationships, which the Action admits.

Claim 8

Claim 8 depends from claim 7/5/3/2/1. The Action (on page 12) admits that Kraft/Liff fails to teach the recited features and relationships (e.g., receiving an input indicative of acceptance of the co-pay amount). Again, even if the teachings of Kraft and Liff were combined as alleged, Kraft/Liff would still fail to teach the recited features and relationships, which the Action admits.

Claim 24

Claim 24 depends from claim 23. The Action (on page 13) admits that Kraft/Liff fails to teach contacting the patient corresponding to the inputted data input corresponding to the patient. Nor has the Action provided any supporting prior art evidence of record. Nor does Kraft/Liff (temporarily) fail to execute. Appellants respectfully submit that in light of the admitted failure of Kraft/Liff to teach or suggest the recited features and relationships, combined with the lack of any other supporting prior art evidence of record, the rejection is not valid.

Claim 25

Claim 25 depends from claim 23. The Action (on page 14) admits that Kraft/Liff fails to teach contacting the physician. Nor has the Action provided any supporting prior art evidence of record. Appellants respectfully submit that in light of the admitted failure of Kraft/Liff to teach or suggest the recited features and relationships, combined with the lack of any other supporting prior art evidence of record, the rejection is not valid.

The Pending Claims Are Not Obvious Over
Kraft in view of Kaufman

Claims 28-31, 34-39, and 42-44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Kaufman. These rejections are respectfully traversed. The Appellants respectfully disagree with the Office's interpretation and application of the references.

Claim 28

Note Appellant's remarks in support of the patentability of claim 34. The Action admits (on page 15) that Kraft fails to disclose or suggest a patient-accessible self-service medical item dispenser. In Kraft it is a nurse which uses the dispenser (12). Even the Action admits (on page 15) that in Kraft it is a nurse which uses the dispenser (12).

Kaufman cannot overcome the admitted and previously discussed deficiencies in Kraft. For example, Kraft is directed to providing secure medical dispensing "to nurses in a hospital setting" (col. 1, lines 5-8). Kaufman is directed to medical dispensing in a "home, outside the support system of a hospital", and without the "supervision of medical personnel" (col. 1, lines 10-14). As discussed in more detail in Appellants' remarks regarding claim 34, one having

ordinary skill in the art would not have found it obvious to have replaced Kraft's secured hospital dispenser with Kaufman's non-secured, non-hospital, in-home dispenser.

The alleged modification to Kraft with the teaching of Kaufman would destroy the explicitly disclosed utility of the Kraft teaching. However, an obviousness rejection cannot be based on a combination of features if making the combination would result in destroying the utility or advantage of the device shown in the prior art references. Note *In re Fine*, 5 USPQ2d 1598-99 (Fed. Cir. 1988). Thus, it would not have been obvious to one having ordinary skill in the art to have modified Kraft with the teaching of Kaufman in the manner alleged to have produced the recited invention of claim 28.

Claim 29

Claim 29 depends from claim 2. With regard to claim 2, the Action (on page 6) admits that Kraft does not teach or suggest data representative of a benefit plan or payment rules associated with the benefit plan. The rejection of claim 2 relied on the teaching of Liff. The rejection of claim 29 does not rely on the teaching of Liff. Where does Kaufman even mention a benefit plan? It follows that neither Kraft nor Kaufman, taken alone or in combination, teach or suggest receiving input from a patient through at least one input device in the manner recited. The Office has not established a *prima facie* case of obviousness.

Claim 30

Claim 30 depends from claim 29/2/1. As previously discussed, the Action relies on the teaching of Liff (which is not applied against claim 30) for the recited features of claim 2. Nor does Kaufman teach or suggest the recited features of claim 2. It follows that the Office has not established a *prima facie* case of obviousness.

Claim 31

Claim 31 depends from claim 30/29/2/1. As previously discussed, the Action relies on the teaching of Liff (which is not applied against claim 31) for the recited features of claim 2. Nor does Kaufman teach or suggest the recited features of claim 2. It follows that the Office has not established a *prima facie* case of obviousness.

The Action alleges that Kraft teaches receiving a payment from the patient corresponding to the at least one medical item requested in the dispense request input. The Appellants respectfully disagree. Kraft does not receive a dispense request input from a patient, but from a nurse. In Kraft it is a nurse which uses the dispenser (12). Even the Action (on page 15) admits that in Kraft it is a nurse which uses the dispenser (12). Again, the Office has not established a *prima facie* case of obviousness.

Claim 34

Kraft does not teach the recited features, relationships, and steps. Note Appellant's remarks in support of the patentability of claim 1. Furthermore, neither Kraft nor Kaufman, taken alone or in combination, teach or suggest the recited features, relationships, and steps.

The Action admits (on page 17) that Kraft fails to disclose or suggest steps (a) and (c). However, it is respectfully submitted that Kraft lacks many more of the recited features and relationships than the Action acknowledges. For example, Kraft also does not teach or suggest steps (b), (d), and (e). Where does Kraft teach or suggest receiving a dispenser input that includes a request to dispense to a patient a medical item prescribed for use by that patient? Where does Kraft teach or suggest verifying with a dispenser that the requested medical item was

dispensed (step (d))? Where does Kraft teach or suggest including in a data store data linking the verified dispensed medical item to that patient (step (e))?

The Action admits (on pages 15 and 17) that Kraft fails to disclose or suggest a patient accessible self-service medical item dispenser that can dispense to a patient (e.g., steps a and c). In Kraft it is a nurse which uses the dispenser (12). As shown in more detail herein, Kraft has fundamental reason for permitting usage of the dispenser (12) to only a nurse. Even the Action admits (on pages 15 and 17) that in Kraft it is a nurse which uses the dispenser (12).

Kraft does not teach or suggest that a patient has access to the dispenser (12), nor that the dispenser dispenses to the patient. Contrarily, Kraft teaches away from the recited invention. Kraft's dispenser (12) is located at a hospital nursing station (col. 3, lines 63-66; col. 5, lines 61-62). That is, the dispenser (12) is intentionally located away from a patient's room.

As is well known, the dispensing and taking of prescribed medical item in a hospital highly controlled. Kraft requires a dispenser that fits into this highly controlled (secure) hospital environment. Kraft's hospital system requires and provides security against unauthorized personnel gaining access to medicine in the dispenser (12). Even a nurse must enter authorized identification, such as a secret password, in order to obtain medication from the dispenser (12) (col. 5, lines 8-11). Thus, Kraft explicitly teaches against using a dispenser to dispense a medical item to a patient, especially a prescribed medical item.

Kaufman cannot overcome the admitted and previously discussed deficiencies in Kraft. Kraft is directed to providing secure medical dispensing "to nurses in a hospital setting" (col. 1, lines 5-8). Kaufman is directed to medical dispensing in a "home, outside the support system of a hospital", and without the "supervision of medical personnel" (e.g., nurses) (col. 1, lines 10-14).

Kaufman's in-home setting is opposite to that of Kraft's hospital setting. It is well known that a patient is admitted into a hospital because care and supervision by medical personnel (i.e., nurses, physicians) is needed. Kaufman's dispenser arrangement includes a plurality of in-home specific features, such as a link to the home's heating and cooling system (col. 7, lines 5-15) and medication dispense commands via a speech recognition system (56) (col. 9, lines 48-53). Kaufman's in-home features for long-term care are not applicable to the short-term care arrangement of a hospital (and insurance companies). A person well enough to use Kaufman's complex (col. 1, lines 9-12) dispenser arrangement would also be well enough to be at home (without required care by a hospital staff), as evidenced by Kaufman's own teaching. It would not have been obvious to one having ordinary skill in the art to have modified Kraft with the teaching of Kaufman in the manner alleged to have produced the recited invention of claim 34.

Kaufman also does not teach or suggest a secure patient-accessible self-service medical item dispenser in a hospital setting. Rather, Kaufman teaches away from Kraft's required secure hospital environment. For example, in Kaufman medication can be dispensed upon demand by the patient (e.g., col. 9, lines 17-25). Where is the security in Kaufman's dispenser arrangement that Kraft requires in the hospital environment? Where does Kaufman teach or suggest that authorized identification, such as a secret password, is required in order to obtain medication from the dispenser (20)? Kaufman's teaches against having a secure patient-accessible self-service medical item dispenser, especially in hospital setting. It would not have been obvious to one having ordinary skill in the art to have replaced Kraft's secured hospital dispenser with Kaufman's non-secured, non-hospital, in-home dispenser.

Nor has the Action provided any evidence of record that a patient accessible self-service medical item dispenser is even legally permitted in a hospital setting, which is the setting in Kraft. The Action also lacks evidence of record that Kraft's dispenser arrangement is even capable of being replaced by Kaufman's dispenser arrangement. For example, how could Kaufman's dispenser arrangement replace the required robotics subsystem (40) and packaging subsystem (38) of Kraft's dispenser arrangement? The packaging subsystem (38) is needed in Kraft in order to directly transfer medication from a container to a package without cross-contamination (col. 2, lines 14-17; col. 14, lines 6-7). Thus, the record lacks substantial evidence support. *In re Zurko*, supra. The Action also procedurally fails to establish a prima facie case of obviousness. *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989).

One having ordinary skill in the art would not have found it obvious to have replaced Kraft's secured hospital dispenser with Kaufman's non-secured, non-hospital, in-home dispenser. The alleged modification to Kraft with the teaching of Kaufman would destroy the explicitly disclosed utility of the Kraft teaching. However, an obviousness rejection cannot be based on a combination of features if making the combination would result in destroying the utility or advantage of the device shown in the prior art references. Note *In re Fine*, supra. Thus, it would not have been obvious to have modified Kraft in the manner alleged. The Office has not established a *prima facie* showing of obviousness. Even if it were somehow possible for Kraft to be modified with the teaching of Kaufman as alleged, the result still would not have produced the claimed invention. Thus, it would not have been obvious to one having ordinary skill in the art to have modified Kraft with the teaching of Kaufman in the manner alleged to have produced the recited invention of claim 34.

Furthermore, neither of the applied references, taken alone or in combination, teach or suggest steps (d) and (e). As previously discussed (Appellant's remarks in support of the patentability of claim 1), Kraft does not teach or suggest verifying (claim 34, step d) that a requested medical item was dispensed, nor including in a data store data linking the verified dispensed medical item to a patient.

Kaufman cannot alleviate the admitted and previously discussed deficiencies in Kraft. Kaufman also does not teach or suggest verifying (claim 34, step d) that a requested medical item was factually dispensed. Nor does Kaufman have any need of verifying that a medical item dispense actually occurred. Thus, neither Kraft nor Kaufman teach or suggest step (d) of claim 34. It follows that the Office has not established a *prima facie* showing of obviousness.

Kaufman also does not teach or suggest recording that a medical item has been verified as dispensed. Nor does Kaufman link a verified dispensed medical item to a patient. Nor does Kaufman record data linking a verified dispensed medical item to a patient. Note claim 34 at step (e). The Action (on pages 15 and 17) admits that Kaufman's dispenser arrangement is for an individual (single) patient. With Kaufman's single patient usage of the dispenser system, what need does Kaufman have for linking a medical item to the single patient, or recording the linking?

Appellants have shown that neither of the applied references, taken alone or in combination, teach or suggest the features and relationships that are specifically recited in claim 34. The Office has not established a *prima facie* showing of obviousness. Additionally, Appellants have shown that it would not have been obvious to modify Kraft with the teaching of Kaufman in the manner alleged. Furthermore, even if it were somehow possible for Kraft to be

modified with the teaching of Kaufman as alleged, the result still would not have produced the recited invention of claim 34. Thus, Appellants respectfully submit the rejection is improper and should be withdrawn.

Claim 35

Claim 35 depends from claim 34. As previously discussed (e.g., Appellant's remarks in support of the patentability of claim 34), Kraft does not teach or suggest verifying (claim 34, step d) that a requested medical item was dispensed. As previously discussed, neither of the references, taken alone or in combination, teach or suggest recording data linking a verified dispensed medical item to a patient. It follows that neither of the references, taken alone or in combination, teach or suggest further recording data linking each of the patient, the dispensed at least one medical item, and location of dispensing the at least one medical item. The Office has not established a *prima facie* showing of obviousness.

Claim 36

Claim 36 depends from claim 34. The Action admits (on page 19) that in Kraft fails to teach dispensing to a patient. Kaufman's dispenser system is for use by a single patient. Even the Action (on page 19) admits that Kaufman's dispenser system is for an individual (single) patient. Neither of the references, taken alone or in combination, teach or suggest a patient-accessible self-service medical item dispenser apparatus capable of dispensing to plural different patients. Nor has the Office established a *prima facie* showing of obviousness.

Claim 37

Claim 37 depends from claim 34. As previously discussed (e.g., claim 36), neither of the references, taken alone or in combination, teach or suggest a patient-accessible self-service

medical item dispenser apparatus capable of dispensing to plural different patients. Neither of the references teach or suggest receiving a dispense request input from a first patient; instructing the first dispenser to dispense the requested medical item to the first patient; receiving a dispense request input from a second patient; and instructing the second dispenser to dispense to the second patient. It would not have been obvious to one having ordinary skill in the art to have modified Kraft with the teaching of Kaufman in the manner alleged to have produced the recited invention.

Claim 38

Claim 38 depends from claim 34. The Action relies on the teaching of Kraft. However, as previously discussed, Kraft does not teach or suggest receiving a patient input with the dispenser (12). Contrarily, in Kraft it is a nurse which uses the dispenser (12), not a patient. Even the Action (e.g., pages 15 and 21) admits that in Kraft it is a nurse which uses the dispenser (12). It follows that neither of the references, taken alone or in combination, teach or suggest receiving with a patient-accessible self-service medical item dispenser a patient payment input. The Office has not established a *prima facie* showing of obviousness.

Claim 39

Claim 39 depends from claim 38/34. It further follows that neither of the references, taken alone or in combination, teach or suggest receiving with a patient-accessible self-service medical item dispenser a patient payment. The Office has not established a *prima facie* showing of obviousness.

Claim 42

Claim 42 depends from claim 38/34. The Action relies on the teaching of Kraft. However, Kraft does not teach or suggest displaying a payment amount to the patient with a display screen of the dispenser (12). As previously discussed, in Kraft it is a nurse which uses the dispenser (12), not a patient. Even the Action (e.g., pages 15 and 21) admits that in Kraft it is a nurse which uses the dispenser (12). It follows that neither of the references, taken alone or in combination, teach or suggest displaying a payment amount to the patient with a dispenser display screen. Nor has the Office established a *prima facie* showing of obviousness.

Claim 43

Claim 43 depends from claim 34. It further follows that neither of the references, taken alone or in combination, teach or suggest determining whether the at least one medical item corresponding to the dispense request input is available for dispensing from the dispenser apparatus.

Claim 44

Claim 44 depends from claim 34. As previously discussed (e.g., claim 34 remarks), neither of the references, taken alone or in combination, teach or suggest verifying that a requested medical item was dispensed. It follows that neither of the references, taken alone or in combination, teach or suggest a sensor sensing a passing of a requested medical item in the manner recited. The Office has not established a *prima facie* showing of obviousness.

Claim 45

As previously discussed (Comment 3), claim 45 is not addressed in the body of the rejection. Furthermore, the reliance on an additional reference (Cummings) in the

Kraft/Kaufman/Cummings rejection of claim 45 infers that claim 45 is not obvious in view of only Kraft/Kaufman. Nevertheless, as shown in more detail hereinafter, claim 45 is not obvious in view of Kraft/Kaufman/Cummings. It follows that claim 45 cannot be obvious in view of only Kraft/Kaufman.

The Pending Claims Are Not Obvious Over
Kraft in view of Kaufman and Cummings

Claims 32-33, 40-41, and 45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Kaufman and Cummings. These rejections are respectfully traversed. The Appellants respectfully disagree with the Office's interpretation and application of the references.

Claim 32

Claim 32 depends from claim 31/30/29/2/1. As previously discussed, the Action (on page 6) admits that Kraft does not teach or suggest data representative of a benefit plan or payment rules associated with the benefit plan (e.g., claim 2). The rejection of claim 2 relied on the teaching of Liff. The rejection of claim 32 does not rely on the teaching of Liff. The Office has not established a *prima facie* case of obviousness. It follows that the rejection, which does not meet the recited features of claim 2, also does not meet the recited features of claim 32.

Furthermore, the Action admits (page 23) that Kraft/Kaufman fails to teach or suggest a card reader device or the recited step (g). Cummings' terminal (11a-11c) has a card data entry slot (52) (col. 7, lines 17-19). The Action relies on Cummings for a card entry slot (52).

Cummings apparently permits the use of a credit card in place of a personnel identification card for purpose of identification (col. 4, lines 40-46). Cummings also apparently permits the use of a credit card for the purpose of data entry (col. 7, lines 25-38). However, Cummings' terminal (11a-11c), even with the relied upon card data entry slot (52), is not associated with a medical item dispenser. Nor does Cummings read a credit or debit card with a card reader device associated with a medical item dispenser step (d). Nor does Cummings charge an account associated with the credit or debit card of step (g). It follows that Cummings cannot alleviate the admitted and previously discussed deficiencies in Kraft/Kaufman. The Office has not established a *prima facie* showing of obviousness.

Claim 33

Claim 33 depends from claim 31/30/29/2/1. As previously discussed (e.g., claim 32 remarks), the Action's relies on Liff for the rejection of claim 2. However, the rejection of claim 33 does not rely on the teaching of Liff. Thus, the Office has not established a *prima facie* case of obviousness.

Furthermore, the Action admits (page 24) that Kraft/Kaufman fails to teach or suggest co-payment or the recited step (f). Cummings does not teach or suggest receiving (claim 31) a co-payment (claim 33) corresponding to a requested medical item (claim 30) prior to dispensing (step d) the medical item from a medical item dispenser. Neither of the references, taken alone or in combination, teach or suggest the recited features, relationships, and steps. Again, the Office has not established a *prima facie* case of obviousness.

Claim 40

Claim 40 depends from claim 39/38/34. The Action states that claim 40 is rejected for the same reason set forth in the rejection of claim 33. Thus, note Appellants' remarks regarding claim 33. Neither of the references, taken alone or in combination, teach or suggest receiving with a patient-accessible self-service medical item dispenser a patient co-payment. Where does any of the references teach or suggest receiving a patient co-payment with a medical item dispenser? The Office has not established a *prima facie* showing of obviousness.

Claim 41

Claim 41 depends from claim 38/34. The Action states that claim 41 is rejected for the same reason set forth in the rejection of claim 32. Thus, note Appellants' remarks regarding claim 32. As previously discussed, the Office has not established a *prima facie* showing of obviousness.

Claim 45

Neither Kraft nor Kaufman, taken alone or in combination, teach or suggest the recited features, relationships, and steps. Note Appellant's remarks in support of the patentability of claims 1 and 34. Furthermore, neither Kraft nor Kaufman nor Cummings, taken alone or in combination, teach or suggest the recited features, relationships, and steps.

The Action admits (on page 26) that the teachings of a patient-accessible self-service medical item dispenser apparatus (step a) and dispensing to the patient (step g) are lacking in Kraft. Thus, the Action admits (on pages 26-27) that Kraft fails to disclose or suggest steps (a), (b), (c), (f), and (g).

The Appellants respectfully submit that Kraft lacks many more of the recited features and relationships than the Action acknowledges. For example, Kraft also does not teach or suggest steps (e), (h), and (i). It follows that Kraft does not teach or suggest any of the steps (a)-(i).

As previously discussed (e.g., claim 34 remarks), it would not have been obvious to have modified Kraft with the teaching of Kaufman in the manner alleged. For example, it would not have been obvious to have modified Kraft with a patient-accessible self-service medical item dispenser (as referred to in steps (a), (b), (d), (f), (g), and (h)). As previously discussed (e.g., claims 3 and 34 remarks) Kraft requires a secure environment (e.g., col. 13, lines 64-66; col. 1, lines 56-67). One having ordinary skill in the art would not have found it obvious to have replaced Kraft's secured hospital dispenser with Kaufman's non-secured, non-hospital, in-home dispenser (e.g., claim 34 remarks).

The Action admits (on page 27) that Kraft/Kaufman fails to disclose or suggest step (d). The Action relies upon Cummings for this allegedly only admitted absent teaching in Kraft/Kaufman. However, the Appellants respectfully submit that Kraft/Kaufman lacks many more of the recited features and relationships than the Action acknowledges. The Appellants respectfully submit that Kraft/Kaufman does not teach or suggest at least steps (b), (d), (e), (h), and (i). For example, where does Kraft/Kaufman teach or suggest receiving patient identification data from a patient (step b); charging an amount (corresponding to a payment associated with a requested medical item type) to an account associated with the credit or debit card (step e); verifying that a medical item type was dispensed to the patient (step h); and including in at least one data store, data linking each of the patient, the verified dispensed medical item type, and the location of the dispensing of the verified dispensed medical item type (step i)? As previously

discussed (e.g., claim 34, step d remarks), Kraft/Kaufman does not teach or suggest verifying that a medical item type was dispensed to a patient (step h). It follows that Kraft/Kaufman cannot teach or suggest storing data linking each of the patient, the verified dispensed medical item type, and the location of the dispensing (step i).

Cummings cannot alleviate the admitted and previously discussed deficiencies in Kraft/Kaufman. Cummings is directed to a health care management system. Cummings is not directed to a medical item dispenser. Nor does Cummings teach or suggest a patient-accessible self-service medical item dispenser (as referred to in steps (a), (b), (d), (f), (g), and (h)). Cummings is non analogous art.

The Appellants respectfully submit that the alleged combination of Kraft/Kaufman/Cummings does not teach or suggest at least steps (b), (d), (e), (h), and (i). Where does Kraft/Kaufman/Cummings teach or suggest receiving patient identification data from a patient (step b); reading a credit or debit card with a card reader device of a medical item dispenser (step d); charging an amount (corresponding to a payment associated with a requested medical item type) to an account associated with the credit or debit card (step e); verifying that a medical item type was dispensed to the patient (step h); and including in at least one data store, data linking each of the patient, the verified dispensed medical item type, and the location of the dispensing of the verified dispensed medical item type (step i)? The Office has not established a *prima facie* showing of obviousness.

The Action (on pages 27-28) relies on Cummings at col. 7, lines 17-37. This portion of Cummings refers to Cummings' terminals (11a-11c). However, these terminals (11a-11c) are conventional data input terminals, such as shown in Figure 2 (col. 4, lines 10-14). The terminals

(11a-11c) are physician office terminals (col. 4, lines 7-10) located within the physician's office (col. 7, line 55). Cummings' terminal (11a-11c) is not a medical item dispenser. Nor is Cummings' terminal a patient-accessible self-service medical item dispenser.

The Action appears to rely on Cummings only for step (d). Thus, the rejection does not provide support for the other noted missing steps. Step (d) of claim 45 is directed to reading a credit or debit card with a card reader device of a medical item dispenser (i.e., a patient-accessible self-service medical item dispenser apparatus). Cummings' terminal (11a-11c) has a card data entry slot (52) (col. 7, lines 17-19). Cummings apparently permits the use of a credit card in place of a personnel identification card for purpose of identification (col. 4, lines 40-46). Cummings also apparently permits the use of a credit card for the purpose of data entry (col. 7, lines 25-38). However, as previously discussed, Cummings' terminal (11a-11c), even with a card data entry slot (52), is not a medical item dispenser. Nor does Cummings read a credit or debit card with a card reader device of a medical item dispenser step (d). Nor does Cummings charge an amount (corresponding to a payment associated with a requested medical item type) to an account associated with the credit or debit card of step (d) (i.e., step e). It follows that Cummings does not teach or suggest step (d) (or step e). Therefore, the Action's reliance on Cummings as a teaching for step (d) is inadequate. Actually, as previously discussed, Kraft/Kaufman/Cummings does not teach or suggest at least steps (b), (d), (e), (h), and (i).

Neither Kraft nor Kaufman nor Cummings, taken alone or in combination, teach or suggest the recited features, relationships, and steps. The Office has not established a *prima facie* showing of obviousness. Additionally, Appellants have shown that it would not have been obvious to modify Kraft with the teaching of Kaufman and Cummings in the manner alleged.

Furthermore, even if it were somehow possible for Kraft to be modified with the teaching of Kaufman and Cummings as alleged, the result still would not have produced the recited invention of claim 45. Thus, Appellants respectfully submit the rejection is improper and should be withdrawn.

CONCLUSION

Each of Appellants' pending claims specifically recites features and relationships that are neither disclosed nor suggested in any of the applied prior art. Furthermore, the applied prior art is devoid of any teaching, suggestion, or motivation for combining features of the applied prior art so as to produce the recited invention. For these reasons it is respectfully submitted that all the pending claims are allowable.

Respectfully submitted,

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APPENDIX OF CLAIMS

1. A method comprising the steps of

(a) storing in at least one data store in operative connection with at least one computer, data representative of at least one patient and at least one medical item prescribed for use by the patient;

(b) storing in the data store, data representative of a plurality of holding locations for medical items in a medical item dispenser, a plurality of types of medical items, and for each of the storage locations, a type medical item stored in the respective storage location;

(c) inputting through an input device in operative connection with the computer and the dispenser, data corresponding to the patient;

(d) dispensing from the dispenser responsive to the data stored in the data store, the type medical item prescribed for use by the patient, wherein the type medical item is dispensed from a storage location holding the type medical item in the dispenser;

(e) including in the data store responsive to execution of step (d), data representative that the type medical item has been dispensed for use by the patient, and that the type medical item has been dispensed from the dispenser.

2. The method according to claim 1 and further comprising the steps of:

storing in the data store, data representative of a benefit plan associated with the patient, and payment rules concerning payment for medical items associated with the benefit plan;

and further comprising the step of charging for the dispensed medical item in accordance with the payment rules.

3. The method according to claim 2 and further comprising the step of:

reading a credit or debit card with a card reading device adjacent the dispenser, wherein the card reading device is in operative connection with the computer, and wherein the charging step includes charging an account associated with the credit or debit card.

4. The method according to claim 2 wherein data representative of a benefits provider is stored in correlated relation with data representative of a benefit plan, and wherein the charging step includes charging the benefits provider.

5. The method according to claim 3 wherein data representative of a benefits provider is stored in correlated relation with the data representative of the benefit plan, and wherein the rules concerning payment associated with the patient include a co-pay requirement associated with the use of the medical item, and further comprising the step of calculating a co-payment amount associated with the medical item, and wherein in the charging step the account is charged the co-pay amount.

6. The method according to claim 5 and further comprising the step of calculating a benefit amount associated with the medical item, and wherein the charging step comprises charging the benefits provider the benefit amount.

7. The method according to claim 5 and prior to the charging step, further comprising the step of outputting through an output device adjacent to the dispenser, indicia representative of the co-pay amount.

8. The method according to claim 7 and prior to the charging step, further comprising the step of receiving through an input device adjacent the dispenser, an input indicative of acceptance of the co-pay amount.

9. The method according to claim 1 and further comprising the steps of:

storing in the data store, data representative of a plurality of benefit plans, and for each benefit plan, corresponding payment rules concerning payment for medical items;

storing in the data store, data representative of a benefit plan associated with the patient;

responsive to input of data corresponding to the patient in step (c), determining responsive to operation of the computer a benefit plan associated with the patient; and

charging for the medical item in accordance with the payment rules associated with the benefit plan determined to be associated with the patient.

10. The method according to claim 1 and prior to step (d) further comprising the step of displaying on an output device adjacent to the dispenser, display indicia including indicia indicative of the type medical item.

11. The method according to claim 10 and prior to step (d) further comprising the step of receiving an input through an input device indicating agreement with the display indicia.

12. The method according to claim 11 and prior to step (a), inputting through a physician terminal in operative connection with the computer, prescription data representative of information that the medical item has been prescribed for the patient, and a medical condition for which the medical item has been prescribed, wherein in step (a) the data stored includes prescription data, and wherein in the displaying step the display indicia includes indicia indicative of the medical condition.

13. The method according to claim 11 and prior to step (a) inputting through a physician terminal in operative connection with the computer, prescription data representative of information that the medical item has been prescribed for the patient and a physician name corresponding to a physician prescribing the medical item for the patient, and wherein in step (a) the data stored includes prescription data, and wherein in the displaying step the display indicia includes indicia indicative of the physician name.

14. The method according to claim 13 and further comprising the step of applying in connection with the dispensed type medical item, indicia indicative of the physician name.

15. The method according to claim 14 wherein the prescription data includes data indicative of an instruction for using the type medical item, and wherein in the applying step, indicia indicative of the instruction for using the type medical item is applied in connection with the type medical item dispensed in step (d).

16. The method according to claim 1 and prior to step (a), inputting through a physician terminal in operative connection with the computer, prescription data representative that the medical item has been prescribed for the patient, wherein in step (a) the data stored includes prescription data.

17. The method according to claim 16 and further comprising the step of applying to the type medical item, indicia indicative of data included in the prescription data.

18. The method according to claim 17 wherein the prescription data includes an instruction for using the type medical item, and wherein in the applying step the indicia applied to the medical item includes indicia indicative of the instruction.

19. The method according to claim 17 and further comprising prior to the applying step, printing a prescription label, wherein the prescription label includes the indicia indicative of the data included in the prescription data, wherein in the applying step the label is applied in connection with the type medical item.

20. The method according to claim 17 wherein the applying step is executed prior to step (d), wherein the indicia indicative of data included in prescription data is applied to the type medical item to be dispensed in step (d).

21. The method according to claim 19 wherein the applying step is executed subsequent to step (d).

22. The method according to claim 21 and further comprising sensing the taking of the label after execution of step (d) wherein the medical item is dispensed, and preventing further dispensing by the dispenser until the label is sensed as taken.

23. The method according to claim 1 wherein step (a) includes storing in the data store, data representative of a plurality of patients, and for each of the patients at least one type medical item prescribed for use by the patient, repeatedly executing steps (a) through (e) wherein data corresponding to different ones of the plurality of patients is input in subsequent executions of step (c), and wherein in each step (d) the type medical item dispensed corresponds to the medical item prescribed for the one patient corresponding to the data input in the step (c) immediately executed prior to the execution of each step (d).

24. The method according to claim 23 and further comprising after executing a particular step (c), failing to execute (d) and further comprising the step of contacting the patient corresponding to the data input in the particular step (c).

25. The method according to claim 23 wherein the data in the data store includes data representative of a physician corresponding to at least one particular medical item prescribed for at least one patient, and wherein in a particular step (c) the data corresponding to the particular patient is input, and thereafter step (d) is not executed, whereby the particular medical item is not dispensed, and further comprising the step of contacting the physician responsive to failing to carry out step (d).

26. The method according to claim 1 and prior to step (d) further comprising the step of checking data in the data store representative of a medical history of the patient corresponding to the data representative of the patient input in either of step (a) or step (c), and determining responsive to the medical history data if the medical item should be withheld from the patient, wherein step (d) is either executed or not executed responsive to the determination made based on the medical history data.

27. The method according to claim 26 wherein the checking step includes communicating over a public data network.

28. The method according to claim 1 wherein the dispenser comprises a patient-accessible self-service medical item dispenser.

29. The method according to claim 2 and further comprising

(f) prior to (d), receiving input from a patient through at least one input device in operative connection with the computer and the dispenser.

30. The method according to claim 29 wherein (f) includes receiving dispense request input from the patient corresponding to at least one medical item prescribed for use by the patient.

31. The method according to claim 30 wherein (f) further includes receiving a payment from the patient corresponding to the at least one medical item requested in the dispense request input.

32. The method according to claim 31 wherein the at least one input device includes a card reader device, wherein the card reader device is in operative connection with the computer, and further comprising

(g) reading a credit or debit card with the card reader device, and charging an account associated with the credit or debit card.

33. The method according to claim 31 wherein the payment comprises a co-payment, wherein (f) includes receiving the co-payment from the patient corresponding to the at least one medical item requested in the dispense request input.

34. A method comprising

(a) storing in at least one data store in operative connection with at least one computer, data representative of each of

at least one patient,

at least one medical item prescribed for use by the at least one patient, and

at least one medical item stored in a patient-accessible self service medical item dispenser apparatus, wherein the dispenser apparatus is operative to receive at least one input from the at least one patient;

(b) receiving at least one input through at least one input device of the dispenser apparatus, wherein the at least one input includes a request to dispense to a first patient at least one medical item prescribed for use by the first patient;

(c) responsive to the request to dispense, instructing the dispenser apparatus to dispense the requested at least one medical item to the first patient;

(d) verifying with the dispenser apparatus that the requested at least one medical item was dispensed;

(e) responsive to the verification, including in the data store, data linking the verified dispensed at least one medical item to the first patient.

35. The method according to claim 34 wherein (e) further includes

responsive to the verification, including in the data store, data linking each of

the first patient,

the dispensed at least one medical item, and

location of dispensing the at least one medical item.

36. The method according to claim 34 and further comprising

(f) receiving another at least one input through the at least one input device of the dispenser apparatus, wherein the another at least one input includes a request to dispense to a second patient at least one medical item prescribed for use by the second patient;

(g) responsive to the request to dispense to the second patient, instructing the dispenser apparatus to dispense the requested at least one medical item to the second patient.

37. The method according to claim 34 wherein the dispenser apparatus includes at least a first dispenser and a second dispenser, wherein (b) includes receiving dispense request input from the first patient through an input device in operative connection with the first dispenser, and further comprising

(f) receiving dispense request input from the second patient through an input device in operative connection with the second dispenser;

(g) responsive to (f), instructing the second dispenser to dispense to the second patient at least one medical item prescribed for use by the second patient;

38. The method according to claim 34 and further comprising

(f) prior to (c), receiving with the dispenser apparatus a patient payment input.

39. The method according to claim 38 and further comprising receiving a patient payment corresponding to the at least one medical item requested in the dispense request input.

40. The method according to claim 39 wherein the patient payment comprises a patient co-payment, and further comprising receiving the patient co-payment corresponding to the at least one medical item requested in the dispense request input.

41. The method according to claim 38 wherein the dispenser apparatus includes a card reader device, wherein the card reader device is in operative connection with the computer, and further comprising

(g) reading a credit or debit card with the card reader device, and further comprising charging an account associated with the credit or debit card.

42. The method according to claim 38 wherein the dispenser apparatus includes a display screen, and further comprising

(g) prior to (c), displaying a payment amount to the patient with the display screen.

43. The method according to claim 34 and further comprising

(f) prior to (c), determining whether the at least one medical item corresponding to the dispense request input is available for dispensing from the dispenser apparatus.

44. The method according to claim 34 wherein (d) further comprises at least one sensor in the dispenser apparatus transmitting at least one signal responsive to the at least one sensor sensing a passing of the requested at least one medical item, and (e) further comprises including in the data store verification of the dispensing of the at least one medical item.

45. A method comprising

(a) storing in at least one data store in operative connection with at least one computer, data representative of each of

a plurality of medical item storage locations in a patient-accessible self service medical item dispenser apparatus,

a plurality of types of medical items,

the type of medical item stored in each respective storage location,

at least one patient, and

at least one medical item type prescribed for use by the at least one patient;

(b) receiving patient identification data from a patient through at least one input device of the dispenser apparatus;

(c) receiving from the patient through the at least one input device a request to dispense at least one medical item type prescribed for use by the patient;

(d) reading a credit or debit card with a card reader device of the dispenser apparatus;

(e) charging an amount to an account associated with the credit or debit card, wherein the amount corresponds to a payment associated with the requested at least one medical item type;

(f) instructing the dispenser apparatus to dispense to the patient the requested at least one medical item type;

(g) dispensing from the dispenser apparatus to the patient the requested at least one medical item type, wherein the at least one medical item type is dispensed from at least one storage location holding the at least one medical item type;

(h) verifying with the dispenser apparatus that the requested at least one medical item type was dispensed to the patient, including at least one sensor in the dispenser apparatus transmitting at least one signal to the computer responsive to the at least one sensor sensing a passing of the requested at least one medical item type;

(i) including in the at least one data store responsive to (h), data linking each of

the patient,

the verified dispensed at least one medical item type, and

location of the dispensing of the verified dispensed at least one medical item type.